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Bridging the Gap: Risk-Based Regulatory Framework for Software as a Medical Device (SaMD) in India

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Abstract: ***Software as a Medical Device (SaMD) is a growing domain in digital health, encompassing AI-enabled wearable devices and mobile applications that perform medical functions independently. While India regulates medical devices under Medical Device Rules (MDR 2017), there is no specific guideline addressing SaMD, particularly AI/ML-driven software and adaptive algorithms. This study performs a gap analysis by comparing IMDRF, FDA, and EU MDR/MDCG guidelines with India's MDR, highlighting gaps in risk classification, lifecycle management, clinical evidence, and post-market surveillance. Based on the findings, a risk-based, lifecycle-oriented SaMD framework for India is proposed, enabling patient safety, regulatory clarity, and alignment with global best practices.***

Keywords: Software as a Medical Device; SaMD; Regulatory Framework; India; AI/ML; Risk-Based Classification; Lifecycle Management

1. Introduction

The growth of wearable health technologies and AI-driven software has revolutionized healthcare delivery by providing real-time monitoring, early diagnosis, and personalized interventions [1,2]. SaMD refers to software intended to perform medical functions independently, without being part of a physical medical device [3].

Globally, regulatory authorities have established specific frameworks for SaMD:

- IMDRF provides risk-based classification and lifecycle guidance [3].
- US FDA issues guidance on clinical evaluation and pre-certification for AI/ML software [4,5].
- EU MDR/MDCG details classification, clinical evaluation, and lifecycle management [6,7].

In India, SaMD is implicitly regulated under MDR 2017, but explicit guidelines for AI/ML-based software, adaptive algorithms, and wearable devices are lacking [8]. This gap creates challenges for manufacturers and potential risks for patient safety.

This study aims to:

1) Compare international SaMD regulations with Indian MDR 2017.
2) Identify gaps in India's SaMD regulatory framework.
3) Propose a risk-based, lifecycle-oriented guideline for India.

2. Methodology

- Document Review: Global SaMD guidance documents from IMDRF, FDA, and EU MDR/MDCG were analyzed [3–7].
- India MDR Analysis: MDR 2017 and CDSCO notifications were reviewed for applicability to SaMD [8].
- Gap Analysis: Key areas considered were risk classification, lifecycle management, clinical evidence, post-market surveillance, and cybersecurity.
- Framework Proposal: A risk-based, lifecycle-oriented guideline for India was drafted based on global best practices and identified gaps.

3. Results

Comparative Analysis of Regulatory Frameworks

Aspect	IMDRF	FDA	EU	India
Definition	Standalone medical software	Same as IMDRF	Standalone or embedded	Not explicitly defined
Classification	4-class IMDRF matrix	Class I–III	Class I–III	Class A–D general; no SaMD-specific matrix
Clinical Evidence	Proportional to risk	Required for moderate/high risk	Mandatory; technical file	Safety/performance required; no software-specific guidance
Lifecycle Management	Recommended	FDA design control, V&V, AI/ML update control	MDCG software lifecycle guidance	MDR 2017 general; no software-specific lifecycle guidance
Post-Market Surveillance	Recommended	Required for moderate/high risk	Required; periodic safety updates	Required; no software-specific guidance
Cybersecurity	Recommended	FDA cybersecurity guidance	MDCG recommends risk assessment	Not addressed

Identified Gaps in India

1) Absence of explicit SaMD definition.
2) Lack of risk-based classification aligned with IMDRF/FDA/EU.
3) No software lifecycle management guidance, especially for AI/ML and adaptive algorithms.
4) Limited guidance on algorithm updates, version control, and real-time performance monitoring.
5) Cybersecurity and patient data protection are not explicitly addressed.
6) Post-market surveillance is not tailored to software performance or AI/ML-based adaptive devices.

4. Proposed Framework for India

4.1 Risk-Based Classification

- Adopt IMDRF-style risk matrix mapped to Indian MDR classes A–D.
- Classes C and D require clinical evidence and CDSCO approval.

4.2 Lifecycle Management

- Design & Development: SDLC documentation, risk assessment, intended use.
- Verification & Validation: Software testing, algorithm validation, clinical evidence.
- Deployment & Post-Market Surveillance: Complaint handling, AI update monitoring.
- Maintenance & Updates: Version control, risk reassessment for algorithm changes.
- Cybersecurity & Data Integrity: Encryption, access control, continuous risk assessment.

4.3 Clinical Evidence

Risk-proportional clinical validation; high-risk SaMD (Class C/D) requires clinical trials or real-world evidence.

4.4 Conformity Assessment

- Class A: Self-certification
- Class B: CDSCO review of technical documentation
- Class C: CDSCO approval with clinical evidence
- Class D: CDSCO approval with extensive validation and periodic audits

5. Discussion

India's current MDR framework does not provide explicit guidance for SaMD, leaving gaps in risk classification, lifecycle management, post-market surveillance, and AI/ML software oversight. Adoption of a risk-based, lifecycle-oriented framework aligned with IMDRF, FDA, and EU MDR ensures:

- Harmonization with international best practices
- Regulatory clarity for manufacturers
- Enhanced patient safety through robust lifecycle management
- Support for innovation in AI-enabled wearable technologies

6. Conclusion

This study identifies critical gaps in India's regulation of SaMD and proposes a comprehensive, risk-based, lifecycle-oriented framework. Implementation of these guidelines will ensure regulatory readiness, patient safety, and global harmonization, while enabling innovation in AI/ML-enabled wearable health devices.

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